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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,078	04/08/2004	Robert A. Davis	56630US007	1677
32692 7590 01/23/2007 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			EXAMINER HAND, MELANIE JO.	
			ART UNIT 3761	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/821,078	Applicant(s) DAVIS ET AL.	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/06, 12/20/06, 1/4/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, page 6, filed November 13 2006, with respect to the rejection(s) of claim(s) 61 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of a previously applied prior art reference.

Applicant's arguments, see Remarks, page 5, with respect to the objection to claims 59, 60 and 62 have been fully considered and are persuasive. The objection to claims 59, 60 and 62 has been withdrawn.

Applicant's arguments filed with respect to the rejection of claims 58-60 and 62-75 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the rejection of the claims under 35 U.S.C. 102: Applicant argues that impermeability to water is not an indication of impermeability to impermeability of ethylene oxide. While this is true if one is considering all phases of water, it is not a true statement if one only considers steam, or water in vapor form. Applicant's citation regarding sterilization does not mention water and only mentions ethylene oxide gas in exemplary language, and not to the exclusion of water. Sterilization of medical equipment manufactured from polyethylene alone or with a layer of polyester can be (and is) routinely accomplished with either of or both steam and ethylene oxide as polyethylene and polyester are only water-vapor permeable and, obviously, also EtO vapor permeable. As stated previously, any material that is water vapor-impermeable will be ethylene oxide vapor-impermeable. Applicant has not set forth an example of a water permeable material (permeable to water either

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of, or both, liquid or vapor form) that is simultaneously impermeable to ethylene oxide as this would constitute proper evidence that a material's permeability to water is not an indicator of permeability to ethylene oxide. It is true that a material being water permeable is not necessarily a testament to its ethylene oxide water vapor-permeability or lack thereof, however it is assured that a material which is impervious to the vapor form of water (as was stated with reference to the barrier layers taught by Dischler in the rejection of claim 58) will be impervious to ethylene oxide vapor as well.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on November 13, 2006, December 20, 2006 and January 4, 2007 were each filed after the mailing date of the Application on April 8, 2004. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Double Patenting

Examiner maintains the provisional nonstatutory double patenting rejection of claims 58 and 61-66 made in the previous Office action.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 58-60 and 62-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Dischler (U.S. Patent No. 6,585,693).

With respect to **Claims 58,64-67,69,70,73,74**: Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. Dischler teaches polymers for the lamina, all of which are substantially water-impermeable (liquid and vapor) and thus will also be impermeable to gaseous ethylene oxide, as an ethylene oxide molecule is larger than a water molecule.

With respect to **Claim 59**: Dischler teaches a syringe body 62 having walls comprised of polymeric lamina and therefore teaches that the barrier covers 100% (i.e. at least 60%) (claim 60) of the walls of body 62. Applicant has not established sufficient criticality for having a barrier material that covers less than 100%, therefore this limitation is considered an optimization of the surface area of said barrier layer(s). It would be obvious to one of ordinary skill in the art to modify the barrier coverage area to be less than 100% as the blister chambers collectively are

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not coextensive with said walls and therefore would only need the barrier functionality in the areas adjacent said chambers. Leaving the remainder free of barrier material would facilitate transparency and visual inspection of said syringe.

With respect to **Claim 62**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claims 63,72,75**: Dischler teaches polyvinylidene chloride (halogenated polyolefin).

With respect to **Claim 68**: Dischler teaches that the barrier lamina are flexible.

With respect to **Claim 71**: Dischler teaches that the polymer lamina are attached to one another via additional heat sealable polymer (heat activated adhesive) lamina therebetween that function also as barrier lamina.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dischler (693).

With respect to **Claim 61**: Dischler does not explicitly teach any of the items set forth in claim 61, but does teach that second chamber 42 contains an injection prep or other sterilizing fluid, of which povidone (iodine complex) and chlorhexidine gluconate are examples that are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to fill second chamber 42 with povidone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 17, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

